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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service M25560

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

April 22, 1999

WARNING LETTER NO. 99-NOL-24

OVERNIGHT DELIVERY
FEDERAL EXPRESS

Mr. Bernard Moore, Owner
Hope African Food Line and Seafood Supply
4324 Downman Road
New Orleans, Louisiana 70126

Dear Mr. Moore:

On October 28-November 3, 1998, an investigator from the U.S. Food and Drug Administration (FDA) conducted an inspection of your dried, smoked catfish processing plant, located at 4324 Downman Road, New Orleans, Louisiana. The investigator documented that your firm was not in compliance with FDA's seafood processing regulations and the Good Manufacturing Practices requirements for foods. This causes your finished products, dried smoked catfish and garfish, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that you failed to operate in accordance with the requirements of Title 21, *Code of Federal Regulations* (CFR), Part 123, covering the Processing and Importing of Fish and Fishery Products and the Current Good Manufacturing Practice (CGMP) regulations for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection of your plant, the FDA investigator observed shortcomings in your system that were nearly identical to those pointed out in the June 10, 1998, inspection and stated in the untitled letter sent to your firm on June 10, 1998. The FDA investigator also provided your firm

with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and the Form FDA 483, which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The observations of concern to us are as follows:

- Failure to provide documentation of the process establishment, as required by 21 CFR Part 123.6(a). We are concerned regarding the potential for the production of toxin by *Clostridium botulinum* during the processing and storage of your dried smoked fish. Documentation must be provided that the critical limits for the drying step result in a water activity of 0.85 or below (21 CFR Part 123.16);

- Failure to have adequate critical limits and monitoring procedures for the control of pathogens in the drying Critical Control Point (CCP), as required by 21 CFR Part 123.6(b) and 21 CFR Part 123.6(c)(4);

- Failure to maintain monitoring records for the drying CCP, as required by 21 CFR Part 123.6(c)(7);

- Failure to maintain sanitation monitoring records, as required by 21 CFR Part 123.11(c); and,

- Failure to have the HACCP plan signed and dated by the most responsible individual, as required by 21 CFR Part 123.6(c)(7).

Objectionable equipment and insanitary conditions, as listed on Form FDA-483 and Form FDA-3501, are an indication that sanitation monitoring [21 CFR 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions include the following:

- The [redacted] saw used in cutting raw and finished product had residues on it from previous operations and was not washed, rinsed and sanitized before use;

- The cooking racks were not washed, rinsed and sanitized before use;

- Metal racks used to hold raw fish were heavily rusted and encrusted with residue;

- No hand sanitizing solutions were present in the receiving area or the drying/smoking room;

- Numerous flies, too many to count, were observed in the receiving area landing on raw catfish being stored outside at various locations until they were prepared for drying/smoking;

- Live flies were noted in the drying/smoking room;

- No hair protection was worn during processing operations;
- The door leading into the drying/smoking room to the outside had an opening at the door to floor juncture that measured approximately 3" x 2'; and,
- Unshielded, ceiling light fixtures were observed directly above the Hobart saw used for cutting raw and dried fish and directly above the gas stove.

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Carolyn S. Olsen, Compliance Officer, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Olsen at (504) 589-7166.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483